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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 936,537	09 13 2001	Gene M Shearer	4239-60808	7176

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,537

Applicant(s)

SHEARER ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1443) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-33 are pending.

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-17, 25 and 28, drawn to a method of specifically inhibiting an immune response by inducing apoptosis, classified in Class 424, subclass 577.
 - II. Claims 1-17, 25 and 28, drawn to a method of specifically inhibiting an immune response by inducing anergy, classified in Class 424, subclass 577.
 - III. Claims 1-17, 25 and 28, drawn to a method of specifically inhibiting an immune response by inducing apoptosis and anergy, classified in Class 424, subclass 577.
 - IV. Claims 18, 19, 26 and 27, drawn to an immunosuppressive composition comprising one or more factors secreted by glioblastoma cells, classified in Class 514 subclass 885.
 - V. Claims 20-23, drawn to a method for enhancing tolerance in a host to an allogenic donor graft, classified in Class 424, subclass 93.1.
 - VI. Claim 24, drawn to a method for enhancing tolerance in a host to an autoantigen, classified in Class 424, subclass 93.7.
 - VII. Claims 29-30, and 32-33, drawn to a method of making an immunosuppressive composition comprising APC, classified in Class 424, subclasses 577 and 93.1.
 - VIII. Claim 31 drawn to an immunosuppressive composition, comprising APC classified in Class 424, subclasses 577 and 93.1.
4. Groups I-III and V-VII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

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5. Groups IV and VIII are different products. Compositions comprising factors secreted by glioblastoma cells and compositions comprising APC differ with respect to the structure of the molecules within the composition, therefore each product is patentably distinct.

6. Groups (IV and I/II/III and (VIII and VI) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case factors secreted by glioblastoma cells of group IV can be used for antibody production and APC of group VIII can be used for production of condition media.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. If Groups I, II or III are elected, applicant is required to elect a specific method of inhibiting an immune response, wherein : A) specific autoimmune disease is selected from the group recited in Claim 11; and B) specific autoantigenic protein is selected from the group recited in Claim 12; and C) specific APC is selected from the group recited in claim 13; D) specific glioblastoma cell is selected from the group recited in Claim 17; D) specific route of administration APC is selected from the group recited in Claim 25.

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These species are distinct because the a specific method of inhibiting an immune response, wherein : A) specific autoimmune disease is selected from the group recited in Claim 11; and B) specific autoantigenic protein is selected from the group recited in Claim 12; and C) specific APC is selected from the group recited in claim 13; D) specific glioblastoma cell is selected from the group recited in Claim 17; D) specific route of administration APC is selected from the group recited in Claim 25 differ with respect to the specific autoimmune disease, specific autoantigenic protein, specific APC , specific glioblastoma cell , specific route of administration APC and the endpoint of the method; thus each specific method employing a specific to the specific autoimmune disease, specific autoantigenic protein, specific APC , specific glioblastoma cell , specific route of administration APC represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

10. If Group IV is elected, applicant is required to elect a specific immunosuppressive composition , wherein : A) loses the ability to induce T cell to undergo anergy or apoptosis is under specific conditions recited in claim 18 (e); B) incubation with specific cells, selected from the group recited in Claim 19.

These species are distinct because their structure, physicochemical properties and conditions are different. The examination of species would require different searches in the scientific literature.

11. If Group V is elected, applicant is required to elect a specific method for enhancing tolerance in a host, wherein APC are obtained from a specific source selected from the group recited in Claim 23.

These species are distinct because a specific method enhancing tolerance in a host, wherein APC are obtained from a specific source selected from the group recited in Claim 23 differ with respect to the specific source of APC thus each specific method employing a specific source of APC represents patentably distinct subject matter. The examination of species would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
December 2, 2002

Christina Chan
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SUPERVISORY PATENT EXAMINER
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